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GG Docket No.: 2C03.1-071  
CIBA Docket No.: SU/V-32766A/CVA

### **REMARKS**

The Office Action mailed October 5, 2005 has been received and reviewed. By the present Response and Amendment, Claims 10, and 18 are amended. No new matter is introduced.

Claims 13, 19-25, 28, and 29 were withdrawn by the Examiner as being drawn to a non-elected invention.

#### **Response to Restriction Requirement:**

Applicants elect, with traverse, to continue prosecution of Claims 1-12, 14-18, and 26-27 (Group I), as required. Pursuant to 37 C.F.R. § 1.143, applicants request reconsideration and withdrawal of the Restriction Requirement for reasons set forth below.

Section 803 of the Manual of Patent Examining Procedure (M.P.E.P.) sets out two criteria for proper requirement of restriction: (1) the inventions must be independent or distinct as claimed; and (2) there must be a serious burden on the Examiner if restriction is required. If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions. MPEP 803.

"Independent," of course, means not dependent. MPEP 802.01. The term "independent" means that there is no disclosed relationship between the two or more inventions claimed, that is, they are unconnected in design, operation, and effect. Two or more inventions are related if they are disclosed as connected in at least one of design (e.g., structure or method of manufacture), operation (e.g., function or method of use), or effect. Examples of related inventions include combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, etc. In this

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definition, the term "related" is used as an alternative for dependent in referring to inventions other than independent inventions.

Related inventions are "distinct" if the inventions as claimed are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER (though they may each be unpatentable over the prior art). MPEP 802.01 (emphasis in original).

The examiner states that Groups I and II are related as "subcombinations usable together in a single combination"; however, this assertion is unclear as the groups are not "subcombinations" nor is there a "combination". Group I includes process claims, and Group II includes articles treated by these processes (product-by-process).

Claim 13 depends from and includes all of the limitations of Claim 1, therefore, it is not independent. Claim 13 should be included in Group I or, at the very least, examined with Group I because no serious burden would be placed on the examiner (as discussed below).

Claim 19 depends from and includes all of the limitations of Claim 14, therefore, it is not independent. Claim 19 should be included in Group I or, at the very least, examined with Group I because no serious burden would be placed on the examiner (as discussed below).

A product defined by the process by which it can be made is a product claim and can be restricted from the process if the examiner can demonstrate that the product as claimed can be made by another materially different process. MPEP 806.05(f). Claims 13 and 19 are items defined by the processes of Claims 1 and 14, respectively, and the examiner has not demonstrated the items "can be made by another materially different process."

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For at least these reasons, the examiner should not restrict Claims 13 and 19 from the Group I claims.

The examiner states that Groups I and III are "related as subcombinations usable together in a single combination"; however, this allegation is unclear as the claims are not "subcombinations" nor is there a "combination." Also the statement "invention I has separate utility such as producing an item without utilizing the complexes of multivalent cations with aromatic structures" has an unclear meaning, especially the term "utilizing." Group I includes process claims, and Group III includes process claims. Is the examiner asserting he is of the opinion that Group III is a species claim within the genus of Group I? If so, a search of Group I would then surely cover the claims of Group III. If the examiner is simply saying there is a different limitation in the Group III claims, this is not a test for proper restriction.

Applicants argue that Groups I and III are not distinct as they are connected in at least one of design, operation, or effect. Therefore, for at least this reason, Group III should not be restricted from Group I.

Additionally, Applicants respectfully submit that the second criteria specified by M.P.E.P. § 803 is not met. Namely, the Examiner would not be seriously burdened by examination of the claims of Groups I and III together. The inventions defined by various claims within Groups I and III are significantly interrelated. As such, in order to properly examine the inventions defined by claims in Group III, it will likely be necessary for the Examiner to search art relevant to claims in Group I as well. Accordingly, there will be no significant additional burden by examination of the claims of Groups I and III together.

The examiner states that different classifications indicate a serious burden of examiner would exist. For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown by appropriate explanation of separate classification,

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or separate status in the art, or a different field of search as defined in MPEP §808.02. However, that *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant. Applicants believe the rebuttal herein is sufficient to overcome any *prima facie* case of burden.

Claim 25 is quite similar to Claim 1. The differences between Claim 25 and Claim 1 (Claim 25 relative to Claim 1) are as follows:

25. A method of processing an item at least partially formed of a hydrophilic polymeric material, containing organic aromatic structures, to produce a reduced protein affinity, said method comprising preventing the formation of [insoluble ionic materials] complexes of multivalent cations with said aromatic structures, in or on the item during processing.

Likewise, Claim 28 is quite similar to Claim 26. The differences between Claim 28 and Claim 26 (Claim 28 relative to Claim 26) are as follows:

28. A method of processing an item at least partially formed of a hydrophilic polymeric material, containing organic aromatic structures, said method comprising inducing the formation of [insoluble ionic materials] complexes of multivalent cations with said aromatic structures, in or on the item during processing.

Therefore, if Claims 1 and 26 fall within Class 264 (Plastic articles shaping and treating)<sup>1</sup>, subclass 1.32 (Lens)<sup>2</sup>, it is unclear why Claims 25 and 28 do not also fall within the same classification and subclass<sup>3</sup> or vice versa (i.e., why Claims 1-12, 14-18, 26-27 do not fall into the same class/subclass as Claims 25 and 28).

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1. Applicants make no admission as to whether these claims are correctly classified.

2. This appears to be an incorrect subclass as 1.32 is directed to polarized lenses only—"processes wherein the polarizing article is a lens or a lens coated with polarizing material." (emphasis added) Maybe subclass 2.6 would be better?

3. Note, however, Claims 1-12, 14-18, and 26-27 are not limited by their language to lens material, nor are Claims 25 and 28.

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Even if Groups I and III fall within different classes, these Groups should be searched and examined together for the reasons discussed above regarding relatedness.

**Species:**

Applicants elect with traverse Group II species, i.e., Claims 1-12 and 14-18, as required by the examiner.

Any search the examiner performs (e.g., either using classification or key word searching), will turn up the same art and be the same search whether the claims are directed toward "preventing the formation of insoluble ionic materials" or toward "inducing the formation of insoluble ionic materials." There is no burden in searching both Groups I and II species as defined by the examiner. The examiner has not demonstrated that any such burden exists.

**Rejoinder:**

Upon allowance of any claims, Applicants respectfully request rejoinder of the claims and species that the examiner has not considered as allowed per the MPEP.

The propriety of a restriction requirement should be reconsidered when all the claims directed to the elected invention are in condition for allowance, and the non-elected invention(s) should be considered for rejoinder. Rejoinder involves withdrawal of a restriction requirement between an allowable elected invention and a non-elected invention and examination of the formerly non-elected invention on the merits. MPEP 821.04. Rejoined claims must be fully examined for patentability in accordance with 37 CFR 1.104.

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**Information Disclosure Statement:**

Applicants respectfully disagree that the IDS filed 17 May 2004 fails to comply with the applicable regulations "because the listed JP document has neither an abstract nor specification in the English language," as stated by the examiner. The regulations do not require references submitted with an IDS to be in English.

37 C.F.R. 1.97, 1.98, and MPEP 609 do not require a translation if applicant is not in possession of one. Applicants need only provide what they have for an IDS. The disclosure requirement does not equate to a need to perform a search or to get a translation. Since no English translation or abstract was in possession of the Applicants at the time, there was no obligation to provide it under any of the cited provisions. The JP document was provided to the Office as it was in the possession of Applicants.

37 CFR 1.98(a)(3)(ii) indicates that if a written English language translation of a non-English language document, or portion thereof, is within the possession, custody or control of a person with a duty to disclose, a copy of the translation shall accompany the statement. See also MPEP 609.04(a). However, no such translation (specification or abstract) was in the possession of a person with the duty to disclose.

Since the information provided by Applicants complies with the requirements for a non-English language document, the document is to be considered by the examiner, and the examiner should not require that a translation be filed by Applicants. See MPEP 609.04(a), 609.05(b).

In spite of there being no requirement by the Applicants to provide an English abstract, the undersigned has made the effort to acquire an English abstract for the Examiner, and a copy thereof has been enclosed herewith. However, Applicants were NOT previously in possession of any English language documents for this reference. Therefore, Applicants respectfully request the examiner consider the JP reference as

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timely submitted and consider it in the same manner as required by the MPEP and regulations.

**35 U.S.C. § 112 Rejections:**

The examiner asserts that the term "elevated" in Claims 10 and 18 is a "relative term, which renders the claim indefinite."

Applicants respectfully traverse this rejection.

Firstly, relative terminology is not *per se* indefinite. Examples of claim language which have been held to be indefinite set forth in MPEP § 2173.05(d) are fact specific and should not be applied as *per se* rules. MPEP 2173.02. The test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). See MPEP 2173.02. The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. Seattle Box Co., v. Industrial Crating & Packing, Inc., 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. MPEP 2173.05(b). "In light of the specification" is not limited to explicit definitions in the specification, but, instead, includes the whole context of the specification. Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in In re Swinehart, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of

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language used to define the subject matter for which patent protection is sought. MPEP 2173.01.

When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement. MPEP 2173.02. See also Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004) ("The requirement to 'distinctly' claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles.

Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite."). The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. MPEP 2173.02.

One of skill in the art would understand the rejected claims based on usage in the art in addition to the context in the specification and claims, especially when considered as



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a whole. Among other things, examples of elevated temperature are given in the specification.

In spite of the fact that the language is not indefinite, the claim language has been amended to expedite prosecution. Support for the amendments can be found, e.g., on page 8 of the current specification.

**35 U.S.C. § 102 Rejections:**

Claims 1, 2, and 8-12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,893,913 [sic, 4,893,918] to Šulc et al.

Applicants respectfully traverse this rejection.

U.S. '918 discloses "hydrogel contact lens or intraocular lens from lightly crosslinked polymers of 2-hydroxyethyl methacrylate, or from such lightly crosslinked copolymers of 2-hydroxyethyl methacrylate where the 2-hydroxyethyl methacrylate units prevail over the units of other virtually non-hydrophilic monomers, and to a method for their production." The lenses are treated with a warm alkaline reacting solution of a salt followed by washing in order to saponify (alkaline hydrolysis) a layer of the lens. This process chemically changes the surface of the lens. '918 discloses a method for production of lenses comprising treating a finally-shaped lens by an alkaline reacting solution of salt and the subsequent removing of all soluble substances from the lens by washing in the treating step (col. 2, lines 8-16). According to col. 2, lines 45-55 of the '918 patent, numerous salts can be used which are soluble in water to concentrated solutions, and these salts specifically include some multivalent cation salts (e.g., those of calcium or magnesium, lines 53-55). Further, this solution must be sufficiently alkaline for the saponification to occur. The purpose of the '918 method is for comfort of lenses.

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The rejection of Claim 1 as written by the examiner implies that Claim 1 reads as the steps of "treating a lens with a hydrophilic surface layer in a solution and washing the lens ... so that the surface becomes protected from deposition of proteins." However, this is not how Claim 1 reads. Instead, Claim 1 is

"1. A method of processing an item at least partially formed of a hydrophilic polymeric material to produce a reduced protein affinity, said method comprising preventing the formation of insoluble ionic materials in or on the item during processing." (emphasis added)

Claim 1 contains the limitation "preventing the formation of insoluble ionic materials in or on the item during processing," which is not explicitly disclosed in '918. The examiner has not pointed to an explicit disclosure in the '918 patent nor where the limitation can be found inherently within the cited reference. See MPEP 2112 for Examiner's burden of proof.

Inherent disclosure requires that an anticipatory inherent feature or result be consistent, necessary, and inevitable, and not merely possible or probable. Also, an accidental achievement of a product or process will not be considered an anticipation. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. See, e.g., In re Rlickaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981); In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries." Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (explaining that

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"[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category").

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

The examiner has not made a case that Claim 1 will be met consistently, necessarily, and inevitably. Therefore, Claim 1 is not inherently anticipated.

The examiner asserts that in the process of Šulc et al. embodiments of the first solution use salts such as sodium phosphate and then asserts that "sodium phosphate is used as the alternative to calcium or magnesium chloride." However, it is unclear on what basis the examiner makes the assertion of "use as an alternative." '918 discloses that the alkaline concentrated salt solution used in its invention can be made with numerous different salts or combinations, including calcium or magnesium chloride (line 55), and the disclosure does not distinguish among various genus, subgenera, or species of salts indicating that all these salts will behave the same way in the '918 method. At most, a genus of alkaline concentrated salt solutions is disclosed by '918. It is taught in '918 that these alkaline concentrated salt solutions saponify the lens.

Based on his assertion of "alternative", the examiner then concludes that "formation of insoluble ionic materials is prevented principally because the components necessary to form insoluble ionic materials are not present." Even if the assertion of "alternative" was supported by the '918 disclosure, the examiner's conclusion regarding prevention of formation of insoluble ionic materials does not necessarily follow from the disclosure of '918 or the present application. It appears the examiner is asserting that '918 or the present application teaches that treating a lens with a solution of sodium phosphate results

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in prevention of "formation of insoluble ionic materials in or on the item during processing" regardless of what else is in that solution or what happens in subsequent steps. No such conclusion is taught or disclosed.

Examiner cites Applicants' specification [00006] for support of his conclusion. However, Applicants' specification [00006] states:

**[00006]** Multivalent anions from the buffer may combine with multivalent cations from the polishing slurry during the lens-polishing step, forming insoluble or sparingly soluble salts, such as calcium phosphate, calcium borate, calcium carbonate, magnesium phosphate and/or magnesium borate inside the matrix of and/or on the surface of the hydrophillic polymeric material. The presence of these insoluble ionic materials in and on a lens has been discovered to increase the attraction and bonding of protein molecules to the lens, thereby increasing protein affinity and the resultant potential for in-eye opacification.

This cited paragraph does not teach (or support) that simply using sodium phosphate rather than calcium or magnesium chloride will prevent formation of insoluble ionic materials, as alleged by the examiner's argument (p. 8, Office Action). Therefore, examiner's conclusion is not supported by the cited section. Disclosure of treating a lens with a genus of concentrated salt solutions (or more specifically, genus of alkaline concentrated salt solutions), among other steps, does not inherently disclose the limitation "preventing the formation of insoluble ionic materials in or on the item during processing." Also, any particular paragraph within the present application cannot be divorced from the rest of the application. The current application discloses various ways that insoluble ionic materials may form on an item (see, e.g., paragraphs [00005], [00006], [00007]) as well as various examples of preventing formation of insoluble ionic materials (see, e.g., paragraphs [00010], [00021], [00022], [00023]).

Also, just because the '918 process may result in a "strongly swollen surface layer ...protect[ing] the lens from deposition of proteins..." (col. 3, lines 4-7), this quotation does

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not mean reduction of protein affinity is achieved the same way by the same method or the same composition as the present invention (i.e., "preventing the formation of insoluble ionic materials"). This section of '918 appears to teach that the swelling is what protects the Šulc lens from deposition of proteins. This does not equate to prevention of "formation of insoluble ionic materials" as required by the language of Claim 1.

Thus, Claim 1 is not anticipated explicitly or inherently, and Applicants respectfully request this rejection be withdrawn.

Claim 2 depends from Claim 1 and includes the additional limitations "hydrating the item in a solution free of multivalent cations; processing the item in the presence of a buffer; and flushing the buffer from the item using a solution free of multivalent cations." '918 does not disclose the limitations of Claim 2. '918 discloses treating a lens with an alkaline concentrated salt solution, not "hydrating the item in a solution free of multivalent cations." In fact, '918 specifically discloses treating a lens with a solution of multivalent cation salts (e.g., those of calcium or magnesium, lines 53-55). The examiner equates "swelling" in '918 with hydrating, but closer reading of '918 shows that the swelling discussed is not synonymous with hydration. The "swelling" of '918 col. 2, lines 13-16 is via water or aqueous solution (either of which can, and frequently do, contain multivalent cations). Examiner's citation to col. 2, lines 56-65 refers to the Šulc treatment with the alkaline concentrated salt solution, not hydration

'918, likewise, does not disclose "processing the item in the presence of a buffer" nor "flushing the buffer from the item using a solution free of multivalent cations." The examiner states the treating occurs with sodium phosphate which "is a buffer" citing col. 2, lines 56-65 and current specification paragraph [00022]. '918 col. 2, lines 56-65 do not teach that sodium phosphate is a buffer, and lines 56-65 only indicate that the salts are "strongly alkaline in aqueous solutions." Paragraphs [00021-00022] of the present application refer to a phosphate buffer (e.g., "preferably a mixture of monosodium

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phosphate and disodium phosphate") and removal of the phosphate ion by subsequent step(s). The examiner states that the '918 lens is "rinsed with water" citing col. 2, lines 8-13 and col. 3, lines 35-36 and equates this to "flushing the buffer... using a solution free of multivalent cations." Col. 2, lines 8-13 do not specify what the '918 is washed with (it does indicate the lens may previously have been swollen with water or aqueous solution prior to reacting). Col. 3, lines 35-36 indicates rinsing a saponified lens and then allowing the saponified lens to swell to equilibrium in distilled or deionized water. This section does not indicate what the lens is rinsed with just what the swelling/equilibrating solution may be, and this step is not "flushing [a] buffer" from the lens.

For at least these reasons, Claim 2 is not anticipated.

Claim 8 depends from Claim 3, therefore, it has all the limitations of Claim 3 in addition to the limitation in Claim 8. If Claim 3 is not anticipated, Claim 8 cannot be anticipated. The examiner has not rejected Claim 3 based on this reference. '918 does not disclose tumble polishing, thus, it cannot disclose tumble polishing with a polishing slurry that is selected from the list of buffers in Claim 8.

Also, examiner's citation to col. 2, lines 45-55 does not teach using an acetate buffer, let alone "a polishing slurry compris[ing] a buffer selected from an acetate buffer...." Col. 2, lines 45-55 are directed toward Šulc's alkaline concentrated salt solution, not a buffer.

For at least these reasons, Claim 8 is not anticipated.

Claim 9, like Claim 8, depends from Claim 3, therefore, cannot be anticipated. Also, examiner's citation is again to Šulc's alkaline concentrated salt solution composition not a "polishing slurry compris[ing] a buffer system of mixed anions." For at least these reasons, Claim 9 is not anticipated.

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Claims 10-11 depend from Claim 2, therefore, for at least the same reasons as Claim 2, these claims are not anticipated. Additionally, Claim 10 includes the recitation "flushing the buffer from the item in a solution free of multivalent cations ...," and Claim 11 includes the recitation "equilibrating the item in a saline solution."

The "processing" referred to by the examiner at col. 3, lines 4-8 is a reference to the saponification reaction of the lens with the alkaline concentration salt solution ("reaction time is very short", emphasis added; see also lines 23-29) not "flushing [a] buffer."

Claim 12 depends from Claim 1, therefore, for at least the same reasons as Claim 1, this claim is not anticipated. Additionally, Claim 12 includes the recitation "step of preventing the formation of insoluble ionic materials in or on the item during processing comprises the exclusion of multivalent cations from a processing solution." As discussed above for Claim 2, '918 does not disclose "the exclusion of multivalent cations from a processing solution." In fact, '918 discloses the inclusion of multivalent cations.

Claim 1 is not limited only to a solution free of multivalent cations, as implied by the Examiner's rejection, but includes a solution free of multivalent anions as well as other offending situations. The current specification teaches that in addition to multivalent cations, multivalent anions also can be offensive (e.g., p. 9, lines 10-15).

### **35 U.S.C. § 103 Rejections:**

Claims 3-6 and 14-18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,893,913 [sic, 4,893,918] to Šulc et al., and further in view of U.S. Patent No. 6,095,901 to Robinson.

Applicants respectfully traverse this rejection.

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Šulc et al. is discussed above. Robinson does not remedy the deficiencies of Šulc et al.

Robinson discloses "[a] method for polishing articles comprising soft acrylic materials... The method includes a polishing step and a cleaning step. In the polishing step, a receptacle is charged with polishing beads of various sizes, alumina, a swelling agent and the articles to be polished, and agitated for a period of time and at a speed sufficient to remove surface irregularities. Following the polishing step, the polished articles are cleaned by agitating them with a cleaning slurry comprising cleaning beads of various sizes, alumina, a solvent and a surfactant for a period of time and at a speed sufficient to clean the surface of the polished articles. Agitation is preferably accomplished by a tumbling machine." The polishing slurry of '901 comprises "polishing beads, alumina, and a swelling agent" (col. 2, lines 24-27). The cleaning slurry of '901 comprises "cleaning beads, alumina, a solvent and a surfactant" (col. 2, lines 35-36)

The legal concept of *prima facie* obviousness is a procedural tool of examination which applies broadly to all arts. It allocates who has the burden of going forward with production of evidence in each step of the examination process. The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. MPEP 2142.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the



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prior art, and not based on applicant's disclosure. The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper. Ex parte Skinner, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986).

The examiner has failed to meet his burden.

Office policy is to follow Graham v. John Deere Co. in the consideration and determination of obviousness under 35 U.S.C. 103. The four factual inquiries for determining obviousness are as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations. When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

- (A) The claimed invention must be considered as a whole;
- (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

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(D) Reasonable expectation of success is the standard with which obviousness is determined. Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

The prior art must suggest the desirability of the claimed invention. "There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432.) If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

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The content of the prior art is determined at the time the invention was made to avoid hindsight. Ascertaining the differences between the prior art and the claims at issue requires interpreting the claim language, and considering both the invention and the prior art references as a whole. In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. MPEP 2141.02. A prior art reference must be considered in its entirety, including portions that would lead away from the claimed invention. MPEP 2141.02.

"Factors that may be considered in determining level of ordinary skill in the art include (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696, 218 USPQ 865, 868 (Fed. Cir. 1983), cert. denied, 464 U.S. 1043 (1984). MPEP 2141.03.

Claims 3-6 depend from Claim 2. Šulc does not teach or suggest the steps of Claim 2 as discussed above. Therefore, any disclosure of Robinson does not remedy this alone or in combination with Šulc. Additionally, there is no motivation to combine Šulc and Robinson because the lens of Šulc has a reduced coefficient of friction, is not irritating to the cornea, and has leveled unevenness of the lens (col. 2, lines 41-44) not "rough spots, sharp edges, and tool or machining marks" as stated by the examiner (p. 9, Office Action).

Šulc does not teach or suggest at least the steps of "hydrating the ocular item in a solution free of multivalent cations; polishing the ocular item in a polishing slurry solution comprising a buffer and a solvent free of multivalent cations; and flushing the buffer from the ocular item using a solution free of multivalent cations" in Claim 14 (as discussed above for Šulc and Claim 2, for example). Therefore, any disclosure of Robinson does not

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remedy this, alone or in combination with Šulc. Additionally, as discussed above, there is no motivation to combine Šulc and Robinson.

Claims 15-18 depend from Claim 14. For at least the same reasons as Claim 14, these claims are not rendered obvious.

Claim 7 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over 4,893,913 [sic, 4,893,918] to Šulc et al. in view of U.S. Patent No. 6,095,901 to Robinson, and further in view of U.S. Patent No. 3,767,788 to Rankin.

Applicants respectfully traverse this rejection.

The standard for making a case under 35 U.S.C. 103(a) is discussed above.

Šulc et al. and Robinson are discussed above. Rankin does not remedy the deficiencies of Šulc et al. and Robinson.

Rankin discloses an ophthalmic solution for treatment of "dry eye." It is an aqueous solution of polyethylene oxide, optionally polyethylene glycol and other optional ingredients.

The disclosure mentions sodium borate as a pH buffer that can be used in the ophthalmic solution when it is used as a medicament carrier for medicaments to be maintained in a basic or neutral medium (col. 5, lines 69-73).

The examiner frequently refers generically to sodium phosphate. There are various sodium phosphate compounds, e.g., monosodium phosphate, disodium phosphate, trisodium phosphate. Šulc refers to trisodium phosphate; Rankin discloses that a combination of monosodium phosphate and disodium phosphate can be made into a buffer. This does not teach that the phosphate buffer of Rankin is interchangeable with an alkaline concentrated trisodium phosphate saponifying solution such as in Šulc. The solutions of Rankin and Šulc are different and used for different purposes.

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Claim 7 is

7. The method of Claim 3, wherein the polishing slurry comprises a borate buffer.

There is no suggestion or motivation to substitute constituents from a medicament to processing steps for producing reduced protein affinity or use in a polishing slurry for tumble polishing an item. Rankin does not suggest or motivate using its pH buffer for use in a polishing slurry for tumble polishing an item, nor do the primary and secondary references. At best, Rankin discloses that sodium borate can be used as a pH buffer.

There is no suggestion/motivation/teaching in Šulc et al. that the sodium phosphate in Šulc et al. is used as a pH buffer (or in particular, "maintaining an alkaline pH" as asserted by the examiner (Office Action, p. 11). Šulc et al. simply discloses that a sodium phosphate (specifically, trisodium phosphate) solution is a salt solution (col. 2, lines 45-55) or that a solution of concentrated trisodium phosphate can be alkaline in aqueous solution (col. 2, lines 57-61)<sup>4</sup>. The purpose of the salt solution of Šulc et al. is not as a pH buffer. Therefore, there is no suggestion or motivation to substitute a sodium borate pH buffer of Rankin for a sodium phosphate salt solution of Šulc et al. (i.e., they are not taught to be "interchangeable to achieve the same end result").

Robinson does not disclose sodium phosphate or sodium borate. The slurries of Robinson comprise a non-aqueous swelling agent or solvent selected from the group consisting of aliphatic hydrocarbons, chlorinated solvents, and aromatic hydrocarbons. Robinson in no way suggests/motivates/teaches anything about sodium phosphate let alone substituting sodium borate for some purpose.

Rankin does not disclose a "polishing slurry compris[ing] a borate buffer." Likewise, Rankin does not suggest to one of skill in the art that a sodium borate pH buffer could or should be used in a "polishing slurry."

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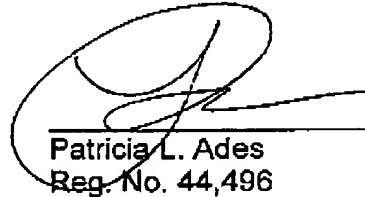
4. '918 also discourages using only the salt to maintain an alkaline pH as the reaction time is extended.

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### CONCLUSION

In view of the amendments submitted herein and the above comments, it is believed that all grounds of rejection are overcome and that the application has now been placed in full condition for allowance. Accordingly, Applicants earnestly solicit early and favorable action. Should there be any further questions or reservations, the Examiner is urged to telephone Applicants' undersigned attorney at (770) 984-2300.

Respectfully submitted,



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